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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,863	10/27/2000	Stefan M C Pye	4555US	7540

24247 7590 09/26/2002

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P.O. BOX 2550  
SALT LAKE CITY, UT 84110

EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 09/26/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/697,863

Applicant(s)

PYPE ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,4,7,11 & 21 are cancelled & 22 is added & 1,3,5,6,8-10,12-20 & 22 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,3,5,6,8-10,12-20 and 22 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3, 5, 6, 19 and 20, drawn to the isolated proteins and a pharmaceutical composition comprising the isolated proteins, are classified in class 530, subclass 300 and class 514, subclass 2.
- II. Claims 8-10, drawn to a polynucleotide, are classified in class 536, subclass 23.1, class 514, subclass 44.
- III. Claims 12-15 and 22, drawn to a method of modulating CD40 signaling pathways comprising an isolated protein and a method of treatment of disease states, are classified in class 514, subclass 2 and class 530, subclass 300.
- IV. Claims 16-18, drawn to a method of screening for a compound that interacts with the isolated protein and the compound produced by the method thereof, are classified in class 424, subclass 9.1, class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct from one another because of the materially different structures of the compounds claimed. The Invention I is drawn to polypeptide whereas Invention II is drawn to a polynucleotide. The biopolymer that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Invention I is related to Inventions III and IV as product and alternative processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product (MPEP § 806.05(h)). In the instant case, Groups III and IV demonstrate alternative methods of use.

Invention II are unrelated to Inventions III and IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the claimed polynucleotide does not practically participate in the mechanism of using the isolate protein for regulation of the CD40 signaling pathways and the mechanism of interaction of the chemical compound with the isolated protein.

Inventions III and IV are directed to different and/or distinct methods each from the other, a method of modulating CD40 signaling pathways comprising an isolated protein, and a method of screening for a compound that interacts with the isolated protein, respectively. Although there are no provisions under the section for "Relationship of Invention" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper among the methods of Inventions II and IV since they constitute distinct inventions comprising methodologies, starting material, objectives, technical considerations, ingredients, endpoint or/and treatment outcome. Each method therefore is patentably distinct.

#### ***Additional Election Under 35 USC 121***

Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed disease state and a single disclosed protein-interacting compound to which claims are restricted; and (2) to list all claims readable thereon including those subsequently added.

(a) If Group I is elected, applicant is required under 35 USC 121 to elect one of an isolated protein, either SEQ ID No. 2 or SEQ ID No. 4 for examination since the proteins indicated by SEQ ID NOs: 2 and 4 are chemically distinct products; in addition, the primary sequence homology for interaction between a member of tumor necrosis factor (TNF) and SEQ

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ID No. 2 protein differs from that required for TNF interaction with SEQ ID No. 4 protein; e.g. the former requires 70-100% sequence homology whereas the latter requires 100% homology. Also, Applicants are required to elect one member of TNF receptor superfamily, e.g. CD4, CD30 or TNF receptor II because these receptors are pharmacologically different/distinct as they interact with different agonist(s) and antagonist(s), and they participate in different cellular signaling pathways, e.g. CD40-mediated signaling events include protein tyrosine phosphorylation and activation of NF- $\kappa$ B while CD30 signaling selectively induces IL-13 production, for example.

(b) If Group III is elected, applicant is required under 35 USC 121 to elect one of a cellular signaling protein related disease treatment from Claim 13, as each signaling pathways and cellular signaling mechanism is distinct/different: each disease treatment is related to biologically different/distinct factors, e.g. TRAF (tumor necrosis factor receptor-associated factor), CD40, NF- $\kappa$ B and c-Jun, e.g. CD40-CD40L interaction plays a pivotal role in the inflammatory regulation of atherosclerosis, whereas TNF-receptor-associated factors (TRAFs) TRAF system plays a role in the pathogenesis of the EBV(epstein-Barr virus)-positive lymphomas that arise in immunosuppressed patients, for example. In addition, Applicants are required to elect one of disease states from Claim 14, as each disease state is distinct and method of treatment would have, absent factual data to the contrary, different/distinct parameters to effect the treatment.

(c) If Group IV is elected, applicant is required under 35 USC 121 to elect one of protein-interacting compound from Claim 16 because of different/distinct specificity, affinity and other thermodynamic and kinetic parameters which are required for a cellular interaction of the compound with TRAF (tumor necrosis factor receptor-associated factor) or CD40 or NF- $\kappa$ B or c-Jun, respectively. Therefore, a method of screening one of each compound would require different methodologies, starting materials, technical considerations and ingredients.

In each of (a) and (b) above, the response should also identify the claims readable thereon

as directed to the elected invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their different classification, art recognized divergent subject matter, separate search, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

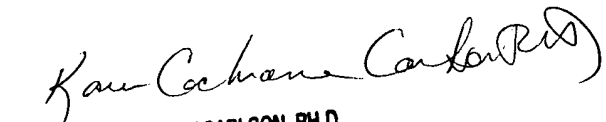
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



SWL

September 14, 2002

  
KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER